

Remarks

The Applicants have amended Claim 17 to include the subject matter of Claim 23. Claim 23 has been cancelled. Claim 17 has also been amended to include aspects with respect to the two zones of difference impedances, the penetration instrument, the signalling means and the contact surfaces. Support may be found in paragraphs 19, 20, 32, 36, 43-45 and 58 of the published application.

Claims 24, 26 and 27 have been amended to depend from Claim 17 in view of the cancellation of Claim 23.

Claim 32 has been added. It is similar to Claim 17 except that it does not contain "means for" language.

This Response is submitted together with a Request for Continued Examination. Entry of the above amendments and new Claim 22 into the official file and consideration on the merits is respectfully requested.

Claims 17-23 and 28-31 stand rejected under 35 USC §103 over the combination of Pearlman with Lum. The Applicants note based on the detailed discussion of the rejection that reference to "Pearlman" is apparently in error and that the rejection intended to refer to "Jenkins." The Applicants will accordingly address the rejection as it applies to a combination of Jenkins with Lum.

The Applicants first note that the rejection of Claim 23 is now moot in view of its cancellation. The Applicants nonetheless respectfully submit that one skilled in the art would not make the hypothetical combination, but in any event, a device resulting from that combination would still be different from the subject matter of Claims 17-23 and 28-31. Details follow.

The Applicants provide a device for forming a hole in a bone structure, while outputting in real time a signal representative of a variation in impedance between two electrodes located on the

penetration instrument. That signal is not perturbed by variations of the depth of entry of the penetration instrument.

In the context of forming a hole in a bone structure, the consequences of a misplacement of the penetration instrument causing damage to surrounding tissues can be very serious, for example, paralysis or hemorrhaging. There is, therefore, an important need to provide for an efficient and reliable signal which can inform the practitioner of the misplacement of the penetration instrument during penetration.

The device of Claim 17 measures the impedance between the contact surfaces of the electrodes during the formation of the hole and emits a real time signal as the penetration instrument passes from the first zone of first impedance to the second zone of second impedance. The signal is, moreover, deprived from perturbations thanks to the invariable dimensions of the contact surfaces arranged within the bone structure.

In sharp contrast, Lum discloses a needle 110 for sampling blood at a desired depth. One of the electrodes formed of an electrically conductive coating 122 has a dimension that increases during the penetration of the penetration instrument. The needle is driven by a processor which moves the needle one step at a time to advance an incremental distance as taught in col. 1, l.49-51, col. 3, l.40-42, 46 to 48, col. 6, l.46-60.

Therefore, Lum fails to disclose at least the following:

- a penetration instrument for forming a hole into the bone structure,
- means for signalling producing a signal at the time a variation in impedance is detected by the means for measuring impedance when the penetration instrument passes from a first of said zones having a first impedance to a second of said zones having a second impedance, so as to inform in real time a practitioner of the position of the penetration instrument, and

- the contact surfaces of the at least two electrodes dimensioned to be constant as a function of a degree of penetration of the penetration instrument in the anatomical structure, said contact surfaces having a dimension along the longitudinal axis that is smaller than that of the hole formed into said bone structure, so that after entry into the bone structure said contact surfaces arranged within the bone structure are invariable during the penetration of the penetration instrument.

On the other hand, Jenkins discloses an implant for electrostimulation of neuroglial, neuromuscular or endo-abdominal tissues or of viscera. The impedance is measured between various pairs of electrodes after the implant has been placed in the tissues to identify and select the pair of electrodes between which a good stimulation will be provided to the tissue as taught in paragraphs 42-44.

Therefore, Jenkins fails to disclose at least the following:

- a penetration instrument for forming a hole into the bone structure,
- means for measuring impedance between the at least two electrodes during penetration of the penetration instrument into said bone structure,
- means for signalling producing a signal at the time a variation in impedance is detected by the means for measuring impedance when the penetration instrument passes from a first of said zones having a first impedance to a second of said zones having a second impedance, so as to inform in real time a practitioner of the position of the penetration instrument, and
- the contact surfaces of the at least two electrodes dimensioned to be constant as a function of a degree of penetration of the penetration instrument in the anatomical structure, said contact surfaces having a dimension along the longitudinal axis that is smaller than that of the hole formed into said bone structure, so that after entry into the bone structure said contact surfaces arranged within the bone structure are invariable during the penetration of the penetration instrument.

The Applicants respectfully submit that those skilled in the art would not make the combination of Jenkins with Lum. In that regard, the Applicants note that neither of Lum nor Jenkins addresses the problem of providing for an efficient and reliable signal which can inform the practitioner of the misplacement of the penetration instrument. Hence, in both of Lum and Jenkins, there is no need for a real time signal deprived from perturbations since the consequence of this placement are much less serious. Hence, one skilled in the art would have had no motivation to combine Lum with Jenkins.

Assuming *arguendo* that one skilled in the art would have combined Lum with Jenkins, the penetration of the instrument for forming a hole and the means for signalling would still be missing. Again, one skilled in the art would not have dimensioned the contact surfaces relative to the hole. The Applicants therefore respectfully request withdrawal of the rejection.

Claims 24-27 stand rejected under 35 USC §103 over the combination of Pearlman with Lum. The Applicants believe that this characterization of the rejection is also erroneous based on the subsequent discussion concerning that rejection. The Applicants believe that the rejection should be over Lum in view of Jenkins in view of Pearlman. The rejection will be treated as such.

The Applicants note that those skilled in the art would not make the combination of Jenkins with Lum and that a device resulting from that combination of Jenkins would still be different from that as recited in Claim 17. The Applicants respectfully submit that Pearlman fails to cure that deficiency.

Pearlman discloses a biopsy needle implementing the measurement of impedance between annular electrodes 156 located on a penetration instrument 154 and a reference electrode located on the body of the patient as taught in paragraphs 157, 159 and 178.

Therefore, Pearlman fails to disclose:

- a penetration instrument for forming a hole into the bone structure,
- at least two electrodes located on the penetration instrument, each of the at least two electrodes having a contact surface coinciding with the surface of the penetration instrument, and
- the contact surfaces of the at least two electrodes dimensioned to be constant as a function of a degree of penetration of the penetration instrument in the anatomical structure, said contact surfaces having a dimension along the longitudinal axis that is smaller than that of the hole formed into said bone structure, so that after entry into the bone structure said contact surfaces arranged within the bone structure are invariable during the penetration of the penetration instrument. The Applicants therefore respectfully request withdrawal of the rejection.

None of Lum, Jenkins and Pearlman addresses the problem of providing for an efficient and reliable signal which can inform the practitioner of misplacement of the penetration instrument. Hence, in all of Lum, Jenkins and Pearlman, there is no need for a real time signal deprived from perturbation since the consequences of misplacement are much less serious. Moreover, since Jenkins does not deal with the issue of penetration, those skilled in the art would not have been taught by Jenkins to dimension the contact surface smaller than the hole formed into the bone structure to have the contact surfaces invariable during the penetration. Thus, those skilled in the art would have no incentive to combine Lum with Jenkins and Pearlman. Withdrawal of the rejection is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'T. Daniel Christenbury', written over a horizontal line.

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